IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL SRL, and ORTHO-MCNEIL, INC.	:	
Plaintiffs,	:	**Case Number: 07-255-JJF**
v.	:	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.	:	
Defendants.	:	

GRÜNENTHAL'S REPLY TO PAR'S OPPOSTION TO MOTION TO QUASH SUBPOENA

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I. ARGUMENT

Par's Answering Brief underscores the propriety of quashing this subpoena as unreasonable and oppressive. The subpoena seeks testimony as part of Par's effort to impose on third party GmbH the burdensome task of producing documents that are available from public sources, are duplicative of documents already produced or are neither relevant nor likely to lead to relevant information. Similar broad categories appear in Par's application for Letters Rogatory. That matter, including the lack of justification and undue breadth, is fully briefed and taken under advisement by this court. Under the circumstances, USA is willing to waive its request for a hearing on July 11 and allow this matter to be decided on the briefs as well.

The principal thrust of Par's Opposition is that the discovery of activity in Germany is needed to show prior invention. Despite Par's continued assertions, it is black letter law that "knowledge and acts in a foreign country are not to defeat the rights of applicants for patents, except as applicants may become involved in priority disputes." *In Re Hilmer* 359 F2d 859, 878 (CCPA 1966)[1] The Par brief chose to ignore this determining factor.[2]

The patent in suit, U.S. Patent 6,254,887 (the '887 patent) is entitled to the benefit of a U.S. filing date of May 10, 1994 and claims the benefit of two priority applications

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[1] §102(a) provides that a "person shall be entitled to a patent unless (a) the invention was known or used by others *in this country*, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

Sections 104 and 101(g) now permit owners and applicants for US patents to rely on the dates of their invention in NAFTA and WTO countries, to establish the priority dates of their own inventions but does not change the basic rule of section 102(a) that only disclosure of a foreign invention in a printed publication can be used by others to defeat the validity of a patent.

[2] Even though Par was responding to assertions that there was lack of justification for the burdensome subpoena categories, it was content to simply and broadly allege that the requested information is "relevant", without even explaining how it could come to that conclusion.

filed in 1993 and two priority applications filed in March, 1994. Prior third party invention, therefore, requires invention in the US in 1993 and before and not later than March, 1994.

The record demonstrates that:

1. GmbH has its own U.S. Patent on a sustained release tramadol product, U.S. Patent 5,601,842, but it is not prior art to the '887 patent. It is a reference only as of its parent's U.S. filing date of September 2, 1994, subsequent to the May 10, 1994 filing date of the '887 patent.[3]

2. GmbH does not market a sustained release tramadol product in the US and USA does not manufacture, sell or service any product. Neither has any connection to the present cause of action.

3. USA has a separate corporate identity from GmbH. Its President is only one of the four member executive board of GmbH. Separate corporate entities are not readily disregarded. *Power Integration, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 233 F.R.D. 143, 145 (D. Del 2005)

4. USA did not come into existence until September 18, 2001, many years after the '887 patent was filed and even after the '887 patent issued on July 31, 2001. Par does not even attempt to suggest that eight year old documents would have been available to USA on demand in the normal course of business to support much later clinical trials of other products.[4]

[3] A patent is a reference under 35 USC § 102(e) only as of its U.S. filing date, not of its foreign priority date. *In re Hilmer*, 359 F2d 859, 878 (CCPA 1966) Par's brief ignored this fundamental patent principle when it asserted "Grünenthal's patent on controlled release tramadol, with a priority date of September 1993, becomes prior art." (p. 4)

[4] In a novel theory, Par asserts the Dr. Paques, as a member of GmbH's board, is likely to have personal knowledge of the GmbH's European development and that knowledge is somehow the corporate USA

Under the precedent of *Playboy Entertainment Group., Inc. v. United States*, 1997 WL 873550 (D.Del. 1997) and *Power Integration*, supra, the above is more than adequate to put an end to Par's attempt to reach GmbH's documents through USA

In addition, the availability of relevant information from other avenues is a factor to be considered. *Power Integration, Inc*., at 146. In this case, a wealth of information is already in Par's possession because of the extensive discovery in this case, or is available from public or alternate sources. Par's Answering Brief singles out examples of its purported need for GmbH discovery. In each of the following cases, the information is already in Par's possession, is available from another source or the information is plainly not relevant.

A. The European opposition proceedings against Euro-Celtique's EP 624,366 and the identity of the art relied on in the opposition.

The records of European opposition proceedings, including the cited art, are available to the public from the European Patent Office. Purdue's Opposition to the Application for Letter's Rogatory reports that thousands of documents relative to the opposition have already been produced (p. 8) and that evidence related to the European opposition was made of record in the '887 U.S. prosecution (p. 14).

B. GmbH's knowledge of the state of the art.

The publicly available index (attached) of the prosecution history of GmbH's sustained release U.S. Patent 5,601,842 demonstrates that GmbH, in fulfillment of its

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knowledge since he is a member of USA's board. Dr. Paques was not personally subpoenaed. Moreover, as the penultimate page of Par's Exhibit I reports, Dr. Paques did not join Grünenthal until 1994.

obligation to identify all relevant prior art, filed Information Disclosure Statements on March 28, 1995 and again on October 12, 1995 identifying art considered to be relevant. That art is identified on the face of U.S. Patent 5,601,842.

C. License from Euro-Celtique to GmbH.

The Purdue Opposition reported that the license agreement dated July 11, 1997, an agreement that related to more than a single patent property, has already been produced in this proceeding (p. 8). Par does not contend to the contrary.

D. The Dissolution Chart.

The Par brief at page 7 sets out a dissolution chart for the GmbH product that purportedly comes from an internal GmbH document. What Par ignores is the fact that essentially the same chart is set forth in the published GmbH U.S. Patent.

E. The Searle Amendment of 1999

Exhibit H is a 1999 trademark license to Searle which is reported to be interested at that time in licensing a once-a-day preparation from Napp.

F. GmbH's internal documents.

Documents regarding a confidential tramadol development conducted in Germany are said in to be necessary to prove "prior invention." However, as developed above, prior inventorship by another party in another country has no effect on the validity of a United States patent. *In re Hilmer*, supra. (There is no priority dispute here.) GmbH's internal reasoning that led to the opposition settlement and the 1997 license are not relevant here and would not be admissible.

CONCLUSION

Par should not be permitted to subject one third party (USA) to an intrusive deposition in its effort to pursue a burdensome document request from a separate third party (GmbH) where the documents sought either (1) are duplicative of ones obtained or obtainable from the parties themselves, or from publicly available sources, or (2) are not legally sufficient to support Par's alleged justification for their importance. The subpoena thus issued in the furtherance of an unreasonable and oppressive strategy by Par should be quashed.

Respectfully Submitted,

Date: June 26, 2008

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08/300,325 SUSTAINED RELEASE DRUG FORMULATION CONTAINING A TRAMADOL SALT

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Transaction History

Date	Transaction Description
03-18-1996	Abandonment for Purposes of Filing an FWC - File Combined with Child Application
03-18-1996	Mail Express Abandonment (During Examination)
03-18-1996	Express Abandonment (during Examination)
11-13-1995	Notice of Appeal Filed
11-13-1995	Request for Extension of Time - Granted
11-15-1995	Mail Advisory Action (PTOL - 303)
11-15-1995	Advisory Action (PTOL-303)
10-12-1995	Information Disclosure Statement (IDS) Filed
10-12-1995	Information Disclosure Statement (IDS) Filed
11-07-1995	Date Forwarded to Examiner
10-12-1995	Amendment after Final Rejection
10-12-1995	Request for Extension of Time - Granted
05-12-1995	Mail Final Rejection (PTOL - 326)
05-12-1995	Final Rejection
03-28-1995	Information Disclosure Statement (IDS) Filed
03-28-1995	Information Disclosure Statement (IDS) Filed
03-07-1995	Date Forwarded to Examiner
02-28-1995	Response after Non-Final Action
02-09-1995	Case Docketed to Examiner in GAU
12-01-1994	Mail Non-Final Rejection
11-09-1994	Non-Final Rejection
10-25-1994	Case Docketed to Examiner in GAU
10-13-1994	Application Captured on Microfilm

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